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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE: BABY FOOD PRODUCTS LIABILITY LITIGATION This Document Relates to: ALL ACTIONS	Case No. 24-md-3101-JSC MDL 3101 Hon. Jacqueline Scott Corley **DEFENDANTS' BACKGROUND BRIEF IN SUPPORT OF THEIR MOTION TO EXCLUDE PLAINTIFFS' GENERAL CAUSATION EXPERTS** **(BRIEF 1)** Date: December 8, 2025 Time: 9:00 a.m. PT Location: Courtroom 8 19th Floor 450 Golden Gate Ave. San Francisco, CA 94102

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STATEMENT OF ISSUES TO BE DECIDED

1. Whether the opinions of Plaintiffs' proffered experts Ms. Priscilla Barr and Dr. Rachael Jones about alleged levels of exposure to lead and arsenic from Defendants' baby foods should be excluded pursuant to Federal Rule of Evidence 702 because the opinions are based on unreliable methods, are not reliably applied to the scientific data the experts considered, and/or do not fit the facts of the case.

2. Whether the opinions of Plaintiffs' proffered experts Dr. Beate Ritz, Dr. Hannah Gardener, Dr. Howard Hu, Dr. Tomas Guilarte, Dr. Michael Aschner, and Dr. Kevin Shapiro that Defendants' baby foods can cause autism spectrum disorder or attention-deficit hyperactivity disorder should be excluded pursuant to Federal Rule of Evidence 702 because the opinions are based on unreliable methods, are not reliably applied to the scientific data the experts considered, and/or do not fit the facts of the case.

INTRODUCTION

The general causation question now before the Court is whether commercial baby foods—manufactured and/or branded by seven different companies—can cause autism spectrum disorder ("autism" or "ASD") or attention-deficit hyperactivity disorder ("ADHD") due to the presence of trace levels of lead and/or arsenic in the fruits, vegetables, and grains from which these foods are made. Because the answer to this question carries serious public health implications, getting the science right is crucial—not only for the parties involved in this litigation but also for all children, parents, and healthcare professionals.

To establish general causation, Plaintiffs must offer scientifically valid epidemiological studies linking the consumption of commercial baby food with an increased risk of autism or ADHD. But as every expert in the case agrees, no such science exists: no study links baby food (commercial, homemade, home grown or otherwise)—or other food—with any harm, let alone the specific harms of autism/ADHD.

Left with this massive gap in the science, Plaintiffs and their counsel instead construct a kind of general causation expert assembly line in which various experts are each handed a small piece of Plaintiffs' theory to try to build into a whole. Plaintiffs' lawyer-driven general causation construct proceeds in two parts. First, Plaintiffs' lawyers imagine a hypothetical child for each of the seven defendants, who (hypothetically) consumes a diet exclusively comprising a limited selection of one Defendant's baby foods, which (the experts then aver) hypothetically results in that child being exposed to a quantifiable "dose" of lead and arsenic from the foods. Second, Plaintiffs' causation experts use that hypothetical "dose" to opine that lead or arsenic "consumption *through* Defendants' baby foods" can be a cause of "harms that manifest as behaviors consistent with a diagnosis" of autism or ADHD. These exposure and general causation opinions lack the analytical rigor required under Rule 702.

Plaintiffs' exposure experts rest their opinions on implausible premises and flawed assumptions. Their output purports to identify alleged daily levels of lead and arsenic to which a hypothetical child would be exposed—but only if that child lived in their imagined world, not any real one, and consumed a diet devised entirely by Plaintiffs' counsel, in (large) quantities determined

solely by Plaintiffs' counsel, day after day, during time periods dictated by Plaintiffs' counsel. This lawyer-concocted methodology fails to account for even the most basic realities: children do not eat the same foods in the same quantities for hundreds or thousands of consecutive days; children do not eat entire servings of each food without any waste every time they eat; and every child will have multiple exposures to lead or arsenic before they ever consume baby food, starting during prenatal development and through breastfeeding, air, water, soil contamination, and house dust. These experts thus apply no reliable methodology—indeed, no scientific methods at all.

The general causation opinions bootstrapped from these exposure opinions suffer from their own fundamental flaws. The experts do not evaluate or rely on studies of the effects of food; rather, Plaintiffs' experts attempt to extrapolate from generic literature assessing body levels of lead or arsenic as measured in a biomarker (like blood, urine, or hair) not tied to source of exposure. To justify that extrapolation, Plaintiffs' experts also invoke studies that measure the extent to which a single vitamin or nutrient in isolation might inhibit absorption or promote excretion of high levels of lead or arsenic or therapeutically promote excretion of absorbed metals. According to Plaintiffs' experts, those studies offer "insufficient" evidence that nutrients *prevent* the "neurotoxic effects" of lead or arsenic from the general environmental sources, and thus make acceptable the experts' methodology of offering causation opinions about baby food without evidence based on studies considering nutrients and other constituents in baby food (or any food). But as Plaintiffs' experts repeatedly acknowledge, food is a complex mixture of numerous components (such as lipids, water, fiber, phytates, proteins, carbohydrates, vitamins, and minerals) that are necessary for healthy neurodevelopment, and Plaintiffs' experts cannot reliably extrapolate from the single nutrient-metal interaction studies they review to the baby-food opinions they offer.

The notion that eating fruits, vegetables, and grains can cause autism or ADHD finds no general acceptance in the scientific community, and none of the Plaintiffs' experts espouses this view outside of this litigation. The failure to account for the realities of food reflects just one of the many analytical gaps between the underlying scientific studies and Plaintiffs' experts' opinions. In addition, Plaintiffs' experts rely on cherry-picked studies that do not evaluate autism or ADHD diagnoses, do not account for the time period in which children eat baby food, do not look at the

relevant population groups, and do not account for the relevant (trace) doses of lead or arsenic that may be present within baby foods. They also entirely fail to account for the key factors that are especially important when evaluating causation for autism and ADHD—like temporality (*i.e.*, the exposure preceding the outcome) and genetics.

Defendants submit three separate briefs in support of their motion to exclude Plaintiffs' experts. *First,* this brief provides an overview of (1) the presence of heavy metals in our larger environment, and how these levels have dramatically decreased over time, (2) the known etiologies of autism and ADHD, (3) the history of this litigation, (4) an overview of Plaintiffs' experts and their opinions, and (5) the legal standards under Rule 702. *Second*, the exposure brief challenges the two witnesses through whom Plaintiffs' counsel purport to model levels of lead and arsenic exposure in the lawyers' hypothetical child based on defendant-specific menus created by Plaintiffs' counsel. *Third*, the causation brief addresses the six witnesses who appear to offer opinions related to whether Defendants' baby food products can somehow cause "harms that manifest as behaviors consistent with a diagnosis" of autism or ADHD.

Although each brief can be referred to individually, Defendants respectfully recommend that the Court read the briefs in that order, as the arguments in each set the stage for subsequent briefs.

BACKGROUND

A. Lead and Arsenic Exposure Is Unavoidable, but Has Sharply Declined in the U.S. in the Past Several Decades

Long before children eat anything, they are exposed to lead and arsenic. As these metals pass through the placenta, beginning *in utero*, every human person is exposed to some level of lead and arsenic. *See* Ex. 33, at 96:20–25, 185:10–186:5 (Gardener MDL Tr.)[1]; Ex. 26, at 44:1–8 (Ritz MDL Tr.); Ex. 34, at 152:18–24 (Aschner MDL Tr.); Ex. 29, at 220:4–14 (Hu MDL Tr.). After birth, the exposure continues, including through breastmilk, tap water, dust, dirt, air, and other sources. Because lead and arsenic are ubiquitous in the environment,[2] exposure to these metals is

[1] Citations to 'Ex. __' are to the exhibits attached to the Declaration of Livia M. Kiser, which is being filed simultaneously herewith.

[2] FDA, *FDA Response to Questions About Levels of Toxic Elements in Baby Food, Following*

unavoidable.

Heavy metal exposures derive from two main sources. First, lead and arsenic, as well as beneficial heavy metals like zinc and iron, occur naturally in the environment and are present in the earth's crust. Ex. 29, at 278:19–280:1 (Hu MDL Tr.). Second, heavy metals have been introduced into the environment through industrial activities, including arsenic mining, and the use of lead in cans, paints, and gasoline.[3]

Both plants and animals absorb heavy metals from the environment through air, soil and water.[4] As a result, many foods—including both commercially manufactured and homemade baby foods[5]—contain trace amounts of heavy metals because they are comprised of ingredients (*e.g.*, fruits, grains, vegetables) that have taken up these trace amounts from the environment.[6] Indeed, any healthful diet including fruits, vegetables, and grains will thus inevitably expose children to some level of heavy metals.

Over the last 30 years, there has been a dramatic reduction in the daily dietary exposure to heavy metals in the U.S., especially for children. For example, FDA has reported that between 1980 and 2016, there was a ***97%*** decrease in daily dietary exposure to lead for 1-3 year-olds.

Congressional Report (Feb. 16, 2021), https://www.fda.gov/food/hfp-constituent-updates/fda-response-questions-about-levels-toxic-elements-baby-food-following-congressional-report ("Because these elements occur in the environment, currently they cannot be completely avoided in the fruits, vegetables, or grains that are the basis for baby foods, juices, and infant cereals made by companies or by consumers who make their own foods.").

[3] *See* FDA, *Lead in Food and Foodwares* (Jan. 6, 2025), https://www.fda.gov/food/environmental-contaminants-food/lead-food-and-foodwares ("Levels of lead in the environment can vary depending on natural geographical makeup and proximity to current or past use or manufacturing of products made with lead. For example, lead has entered the environment from the past widespread use of lead in paint, gasoline, and plumbing materials, as well as many other products.").

[4] *See id.* ("Lead may be present in food from the environment where foods are grown, raised, or processed."); FDA, *Arsenic in Food* (Mar. 5, 2024), https://www.fda.gov/food/environmental-contaminants-food/arsenic-food ("Arsenic may be present in food from the environment where foods are grown, raised, or processed.").

[5] *See* Healthy Babies Bright Futures, *Is Homemade Baby Food Better?* (Aug. 2022), https://hbbf.org/sites/default/files/2023-03/BabyFoodReport2022_R11_Web.pdf.

[6] FDA, *FDA Shares Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies and Young Children* (Apr. 8, 2021), https://www.fda.gov/food/hfp-constituent-updates/fda-shares-action-plan-reducing-exposure-toxic-elements-foods-babies-and-young-children ("Making your own baby foods is not likely to reduce your baby's risk of exposure to toxic elements in food. It may actually result in higher concentrations of toxic elements.").

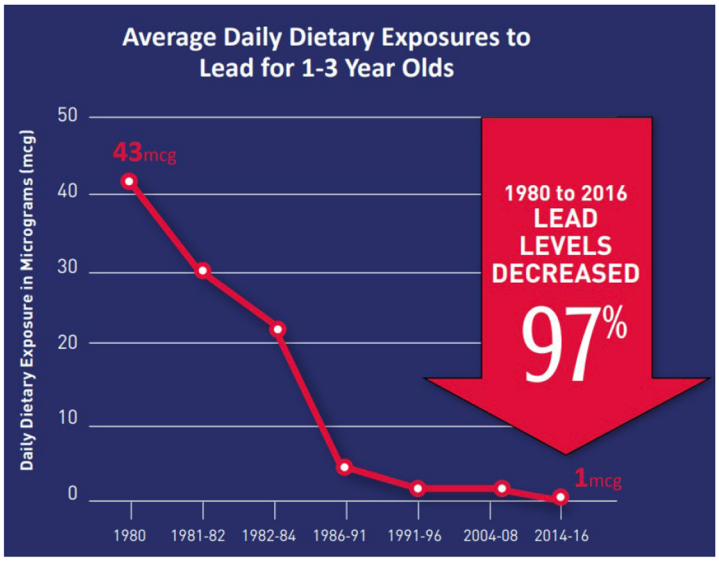

Figure 1. Reductions in average daily dietary exposures to lead for 1-3-year-olds from 1980 to 2014-2016 (FDA, *Lead in Food, Foodwares, and Dietary Supplements* (Jan. 2023)).

Additionally, the Centers for Disease Control and Prevention ("CDC") found that, between 1978 and 2016, there was a significant reduction in blood lead concentrations in children in the U.S.

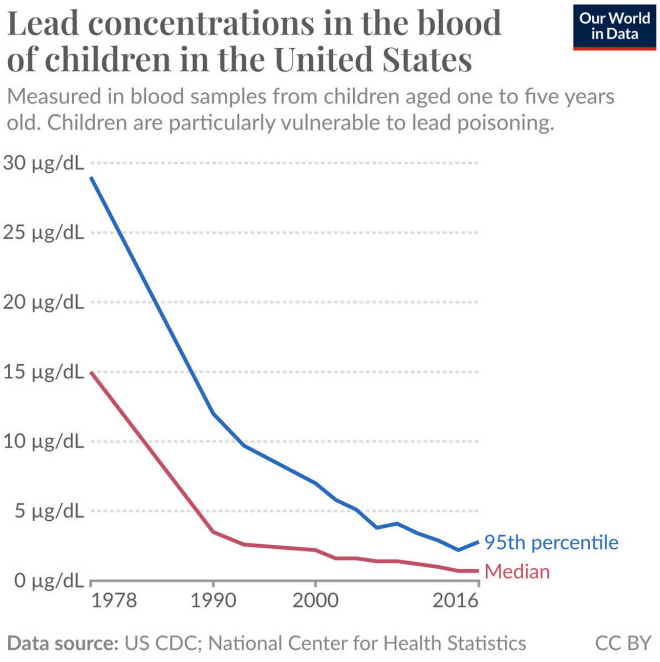

Figure 2. Blood lead concentrations in U.S. children from 1978-2016 (CDC, National Center for Health Statistics)

The CDC, based on its rigorous scientific standards and research, has responded to this decline by repeatedly lowering its benchmark for "normal" blood lead levels. Between 1960 and

1990, the blood lead level for intervention in children was lowered from 60 µg/dL (micrograms/deciliter) to 25 µg/dL. In 1991, the CDC lowered the level of concern further.[7] In 2012, CDC adopted a blood lead "reference value" ("BLRV") of 5 µg/dL, meaning at that time, 97.5% of U.S. children aged 1-5 years had a blood lead level less than that amount.[8] Today, the reference value is 3.5 µg/dL[9] and the mean blood lead level is 0.83 µg/dL for children 1-5 and 0.60 µg/dL for children 6-11.[10] These significantly lowered blood lead levels are principally due to restrictions on lead in gasoline, paint, and can solder.[11] Likewise, although there is no evidence of widespread elevated levels of arsenic in children in the U.S., federal regulatory authorities have set precautionary levels to help reduce children's exposure to inorganic arsenic (the toxic form of that metal).[12]

For decades, FDA has monitored potential exposures to trace levels of lead, arsenic, and other heavy metals—as well as essential vitamins and other minerals—from consuming baby foods with fruits, vegetables, grains, and other ingredients, as well as other foods and food ingredients. As part of FDA's ongoing "Total Diet Study," FDA continuously collects and analyzes the levels of nutrients (such as calcium and iron) and non-nutrient metals (such as lead or arsenic) in approximately 280 different foods and beverages, including commercial baby food products.[13] FDA

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[7] CDC, *Preventing Lead Poisoning in Young Children: A Statement by the Centers for Disease Control* (Aug. 2005), https://stacks.cdc.gov/view/cdc/147840.

[8] CDC, *Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention* (Jan. 4, 2012), https://stacks.cdc.gov/view/cdc/11859.

[9] CDC, *CDC Updates Blood Lead Reference Value* (Apr. 2, 2024), https://www.cdc.gov/lead-prevention/php/news-features/updates-blood-lead-reference-value.html.

[10] Kathryn B. Egan et al., *Blood Lead Levels in U.S. Children Ages 1-11 Years, 1976-2016*, 129 Env. Health Persp. (Mar. 17, 2021), https://ehp.niehs.nih.gov/doi/10.1289/EHP7932?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

[11] Timothy Dignam et al., *Control of Lead Sources in the United States, 1970-2017: Public Health Progress and Current Challenges to Eliminating Lead Exposure*, 25 J. Pub. Health Manag. Pract. S13 (2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC6522252/pdf/nihms-1006171.pdf.

[12] EPA, *Chemical Contaminant Rules* (Oct. 30, 2024), https://www.epa.gov/dwreginfo/chemical-contaminant-rules (arsenic standard in drinking water of 10 ppb, which replaced the prior standard of 50 ppb in 2001); FDA, *Inorganic Arsenic in Rice Cereals for Infants: Action Level Guidance for Industry* (Aug. 2020), https://www.fda.gov/media/97234/download.

[13] FDA, *Total Diet Study Report, Fiscal Years 2018-2020 Elements Data* (July 2022), https://www.fda.gov/media/159745/download?attachment.

has tested thousands of commercial baby food products over the years and gathered comprehensive information about the presence and amount (if any) of these metals in those foods. FDA has also developed a plan called "Closer to Zero," which is a comprehensive multi-year plan to further assess and evaluate potential measures, using reliable science, to continue to drive levels of heavy metals in foods for infants and young children as low as possible while maintaining consumers' access to nutritious foods.[14] In June 2023, FDA issued a final action level for inorganic arsenic in apple juice, and in January 2025, FDA issued final action levels for lead in processed food intended for babies and children.[15] At no point has FDA, or any other public health agency or medical society, suggested that eating fruits, vegetables, or grains is harmful or can cause autism or ADHD.[16]

B. Background on Autism and ADHD

During the time that exposure to lead and arsenic has fallen precipitously for children in the United States, rates of diagnosis of autism and ADHD have increased. The prevalence of diagnosed autism has increased from 1 in 150 in 2000 to 1 in 31 in 2022;[17] and an additional one million U.S.

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[14] FDA, *Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods*, https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods.

[15] FDA, *Action Level for Inorganic Arsenic in Apple Juice: Guidance for Industry* (June 2023), https://www.fda.gov/media/86110/download; FDA, *Action Levels for Lead in Processed Food Intended for Babies and Young Children: Guidance for Industry* (Jan. 2025), https://www.fda.gov/media/164684/download.

[16] *See* FDA, *FDA Letter to Industry on Chemical Hazards, including Toxic Elements, in Food and Update on FDA Efforts to Increase the Safety of Foods for Babies and Young Children* (Mar. 5, 2021), https://www.fda.gov/food/hfp-constituent-updates/fda-letter-industry-chemical-hazards-including-toxic-elements-food-and-update-fda-efforts-increase (reassuring "parents and caregivers that at the levels we have found through our testing, children are *not at an immediate health risk* from exposure to toxic elements in foods" and informing parents and caregivers not to eliminate foods as doing so "may result in deficiencies in certain nutrients and potential poor health outcomes") (emphasis added); CDC, *About Childhood Lead Poisoning Prevention* (Aug. 21, 2025), https://www.cdc.gov/lead-prevention/about/index.html ("Some children are at a greater risk for lead exposure from paint, water, soil, some imported items and industrial sources."); Bruce Perrin Lanphear et al., AAP Policy Statement, *Prevention of Childhood Lead Toxicity*, 138 Pediatrics e20161493 (July 1, 2016), https://publications.aap.org/pediatrics/article/138/1/e20161493/52600/Prevention-of-Childhood-Lead-Toxicity.

[17] CDC, *Data and Statistics on Autism Spectrum Disorder* (May 27, 2025), https://www.cdc.gov/autism/data-research/index.html.

children aged 3-17 received an ADHD diagnosis in 2022 compared to 2016.[18] Although children with autism often have an attendant ADHD diagnosis, autism and ADHD are treated as separate conditions diagnosed using different criteria.[19]

C. Autism/ASD

Autism is a neurodevelopmental condition characterized by certain deficits in social communication skills, and restricted, repetitive patterns of behavior, interests, or activities.[20] The current version of the DSM, DSM-5, sets out the five diagnostic criteria necessary for ASD: (1) persistent deficiencies in social communication and social interaction across multiple contexts; (2) restricted, repetitive patterns of behavior, interest, or activities; (3) symptoms present in the early developmental period; (4) symptoms cause clinically significant impairment in social, occupational, or other important areas of current functioning; and (5) these disturbances are not better explained by intellectual disability or global developmental delay.[21] Over the last twenty years, scientific research has increasingly focused on the genetic etiology of autism. The research indicates that autism is one of the most heritable of disorders.[22] The DSM-5 identifies only three environmental risk factors (*i.e.*, risk factors other than genetics) for ASD, all of which are tied to prenatal development: "advanced parental age, low birth weight, or fetal exposure to valproate."[23]

The diagnosis of ASD is made by a qualified medical professional evaluating the behaviors and developmental history of an individual aided by standardized testing instruments, such as the Autism Diagnostic Observational Schedule ("ADOS") and the Autism Diagnostic Interview-

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[18] CDC, *Data and Statistics on ADHD* (Nov. 19, 2024), https://www.cdc.gov/adhd/data/index.html.
[19] Ex. 58, at 64 (DSM-5).
[20] *Id.* at 31.
[21] *Id.* at 50–51.
[22] D. Bai et al., *Association of genetic and environmental factors with autism in a 5- country cohort*, 76 JAMA Psychiatry 1035 (2019), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2737582; B. Tick et al., *Heritability of autism spectrum disorders: a meta-analysis of twin studies*, 57 J. Child Psychology & Psychiatry 585 (2016), https://acamh.onlinelibrary.wiley.com/doi/10.1111/jcpp.12499; *see also* Ex. 58, at 57 (DSM-5) (citing heritability studies, based on twin concordance rates, estimating that the heritability of ASD (that is, the rate at which genetic factors account for an ASD diagnosis) ranges from 37% to over 90%).
[23] Ex. 58, at 56 (DSM-5).

Revised ("ADI-R"). Critically, the results of these standardized tests are combined with a comprehensive clinical evaluation, including a physical examination, to make a valid diagnosis. Notably, a diagnosis of ASD cannot be made based on self-reported symptoms alone or other discrete measures such as any perceived reduced intellectual quotient ("IQ").

The average age of diagnosis of children with ASD in the U.S. is currently about four years of age.[24] But children diagnosed with autism may show behaviors, like abnormal eye gaze, reduced orientation to name, reduced facial expressions, difficulty shifting attention away from objects, a preference for non-social stimuli, and atypical sensory-motor development, much earlier if assessed by a trained professional.[25] Children with ASD may or may not have other neurocognitive conditions, and frequently have average (or above-average) IQs.[26]

Notably, children with autism may face higher exposure to heavy metals than a neurotypical child *as a consequence of* the disorder itself. Restrictive eating behaviors and pica (*i.e.*, ingesting non-food items including soil or paper) are more common in children with ASD, which can contribute to higher levels of lead and arsenic ingestion.[27] Children with ASD also tend to have nutritional deficiencies due to selective eating behaviors resulting in nutritional deficits, including lower intake of nutrients such as proteins, calcium, phosphorus, vitamin D, thiamine, riboflavin, and vitamin B12.[28] Ex. 35, at 190:22–191:5 (Guilarte MDL Tr.). These nutritional deficiencies, in turn,

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[24] Matthew J. Maenner et al., *Prevalence and Characteristics of Autism Spectrum Disorder Among Children Aged 8 Years — Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2020*. 72 MMWR Surveill. Summ. 1-14 (2023), https://www.cdc.gov/mmwr/volumes/72/ss/pdfs/ss7202a1-H.pdf; Kelly A. Shaw et al., *Prevalence and Early Identification of Autism Spectrum Disorder Among Children Aged 4 and 8 Years — Autism and Developmental Disabilities Monitoring Network, 16 Sites, United States, 2022*, 74 MMWR Surveill. Summ. 1-22 (2025), https://www.cdc.gov/mmwr/volumes/74/ss/pdfs/ss7402a1-H.pdf.

[25] Ex. 59 (Zwaigenbaum et al., 2005); Ex. 58, at 54–56 (DSM-5).

[26] Ex. 58, at 54–55, 58 (DSM-5).

[27] V.L. Fields et al., *Association between pica and gastrointestinal symptoms in preschoolers with and without autism spectrum disorder: Study to Explore Early Development*. 14 Disability and Health J. 101052 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8504874/; N.M. Papini et al., *Prevalence and recurrence of pica behaviors in early childhood within the ALSPAC birth cohort*, 57 Int. J. Eat. Disord. 400 (2024), https://onlinelibrary.wiley.com/doi/10.1002/eat.24111.

[28] Ex. 60 (Sharp et al., 2013); Ex. 61 (Esteban-Figuerola et al., 2019).

can lead to increased absorption of heavy metals. *See id.* at 192:2–8; 166:25–167:5; 169:18–170:9; Ex. 29, at 170:4–8 (Hu MDL Tr.).

As already noted, the rise in U.S. autism diagnoses over the past decades is inversely correlated with blood lead levels. The rate of diagnosis of ASD has steadily increased over the past four decades while lead exposure in U.S. children has decreased dramatically. Although the public health community is studying why ASD diagnoses have increased, there is agreement that at least some of the growth is due to the expansion of diagnostic criteria and increased screening.[29] Ex. 37, at 326:9–20 (Shapiro MDL Tr., Vol. II).

D. ADHD

ADHD is a different neurodevelopmental disorder with symptoms of impairing and persistent levels of inattention, disorganization, and/or hyperactivity-impulsivity.[30] ADHD is also highly heritable, but typically diagnosed later than autism—often when children begin school and are expected to pay attention in class.[31] The manifestations of ADHD must be present in more than one setting (*e.g.*, home and school).[32] ADHD and ASD are often comorbid conditions, as both "individuals with ADHD and those with [ASD] exhibit inattention, social dysfunction, and difficult-to-manage behavior."[33] Nevertheless, the DSM-5 states that the "social dysfunction and peer rejection seen in individuals with ADHD must be distinguished from the social disengagement, isolation, and indifference to facial and tonal communication cues seen in individuals with [ASD]."[34] Like ASD, ADHD diagnoses have steadily increased over the past decades while blood lead levels have declined.[35]

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[29] Public Health On Call, Johns Hopkins Bloomberg School of Public Health, *Is There an Autism Epidemic?* (June 6, 2025), https://publichealth.jhu.edu/2025/is-there-an-autism-epidemic.
[30] Ex. 58, at 32 (DSM-5).
[31] *Id.* at 62 (noting that ADHD is "most often identified during elementary school years").
[32] *Id.* at 61.
[33] *Id.* at 64.
[34] *Id.*
[35] Guifeng Xu et al., *Twenty-Year Trends in Diagnosed Attention-Deficit/Hyperactivity Disorder Among US Children and Adolescents, 1997-2016*, 31 JAMA Netw. Open e181471 (2018), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2698633.

PLAINTIFFS' CLAIMS

This MDL proceeding is the latest in a series of products liability cases attempting to conjure a link between ASD and consumer products. *See generally, e.g.*, *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328 (Fed. Cir. 2010) (involving claims that the measles-mumps-rubella [MMR] vaccine causes autism); *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, 707 F. Supp. 3d 309 (S.D.N.Y. 2023) (involving claims that consumption by pregnant women of acetaminophen causes ASD and ADHD). Here, after staff of the U.S. House of Representatives' Subcommittee on Consumer Policy issued a report regarding the presence of heavy metals in the fruits, vegetables, and grains used in baby and toddler foods,[36] plaintiffs filed a wave of litigation alleging that commercially available baby and toddler foods cause autism and/or ADHD. These cases have been filed at both the state and federal level, some of which are individual suits and some are consolidated actions, like this multi-district litigation. *See, e.g.*, *N.C. v. Hain Celestial Group*, No. 21STCV22822 (Cal. Super. Ct.); *Landon R v. Hain Celestial Group*, No. 23STCV24844, JCCP 5317 (Cal. Super. Ct.). More than 200 cases are part of this MDL.

Plaintiffs claim that the consumption of Defendants' commercial baby food products—which themselves are not a monolithic entity but instead hundreds of different products with scores of different ingredients—caused their children's ASD and/or ADHD. Nearly all the children at issue consumed different baby foods from at least several defendants.[37] And ***none*** of the children consumed baby food in the manner hypothesized by the "menus" created by Plaintiffs' counsel and relied on by their exposure experts.

Although Plaintiffs originally alleged harm from lead, arsenic, cadmium, mercury, and aluminum, Plaintiffs now offer expert testimony on only two heavy metals: lead, which they claim can cause both autism and ADHD, and arsenic, which they claim can cause autism but *not* ADHD.

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[36] Subcomm. on Economic and Consumer Policy, Comm. on Oversight and Reform, H. Rep., *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf.

[37] Out of 229 short-form complaints filed as of September 26, 2025, 91% (209 out of 229) list multiple defendants.

Plaintiffs have abandoned their claims as to cadmium, mercury, and aluminum as none of Plaintiffs' experts assert that these heavy metals in baby food are associated with (much less cause) either autism or ADHD. Without any expert opinions, these claims fail as a matter of law, because all states require expert testimony to support such claims.[38]

A. Plaintiffs' Experts

Plaintiffs named two experts to opine on issues related to the purported level or "dose" of lead and/or arsenic that U.S. children could be exposed to from consuming certain of Defendants' baby food products, and six experts to opine on issues related to whether exposure to those metals could cause "behaviors diagnosable as" ASD or (for lead only) ADHD. Five of those experts purport to link their opinions to Dr. Jones' numbers, whereas a sixth, Dr. Shapiro, does not even mention Dr. Jones in his report. Plaintiffs also proffered opinions from a genetics expert, Dallas Reed. But Dr. Reed made clear that she is not offering any opinions about heavy metals and ASD/ADHD risk. She testified, "I'm not even here to be a causation expert." Ex. 38, at 117:1–14 (Reed MDL Tr.).[39] Consequently, Dr. Reed's opinions are not relevant to this stage of the litigation and Defendants' Rule 702 motion does not address Dr. Reed.[40]

B. Exposure Experts

Plaintiffs proffer two experts to address the issue of exposure, Priscilla Barr, a dietician; and Rachael Jones, Ph.D., an exposure scientist. They were tasked with reviewing seven hypothetical menus—one for each Defendant's baby food products—as a foundation for establishing "dose."

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[38] As the Court has directed, Defendants will file summary judgment motions on these issues after the December Rule 702 hearings.

[39] Of note, Plaintiffs' counsel chose to offer Dr. Reed as a genetics expert instead of their previous genetics expert, Dr. Dmitriy Niyazov, a medical geneticist and Associate Professor of Pediatrics at Duke University, who recently testified in the California state court baby food litigation that:

> **There's no cause of autism that's been established. I just want to make sure you understand, we still don't know what the cause of autism is. But this is all speculation and evidence, and we're just trying to say what is more likely and less likely; what kind of evidence we have or don't. But we don't have a specific cause of autism.**

Ex. 50, at 84:2–85:12 (Niyazov Landon R. Tr.).

[40] As Defendants understand Dr. Shapiro's opinions, they also should not be relevant at this stage of the proceedings. However, Dr. Shapiro is included insofar as he purports to have some views of a generic nature. *See* Section IV.B.3.

Neither Ms. Barr nor Dr. Jones had any involvement in creating these menus. *See, e.g.*, Ex. 39, at 93:6–13 (Barr MDL Tr., Vol. I) ("I did not create the menus."); Ex. 41, at 83:4–13 (Jones MDL Tr., Vol. I) ("I did not participate in the development of the menus."). Instead, Plaintiffs' counsel created these menus and also directed those experts to accept a set of lawyer-created assumptions about how, what, and when infants and toddlers actually eat. These included assumptions related to brands, quantities, age ranges, and calendar years of baby foods consumed. Both Ms. Barr and Dr. Jones were told to assume, rather implausibly, that the child consuming each hypothetical menu was exclusively formula-fed and did not ever consume any breast milk.

Ms. Barr limited her evaluation as to whether each of the hypothetical menus was "plausible," which she interpreted to mean only that it was "possible" that "a child" or "any child" in the U.S. could have had such a diet, expressly disclaiming any notion that the menus were realistic or representative of any U.S. child. Ex. 39, at 123:25–124:8 (Barr MDL Tr., Vol. I) ("[I]t was just about being nutritionally plausible. So that's – ***could a child consume this, like any child***.") (emphasis added); *see also id.* at 129:20–24, 145:25–147:3, 172:19–173:10.

Dr. Jones then used each of the hypothetical menus and the assumptions directed by counsel, without any independent scrutiny or analysis on her part, to calculate daily intake levels of lead and arsenic that a hypothetical infant would be exposed to, by such hypothetical menu, ***if*** every day that infant consumed entire servings (sometimes unrealistically high multiple servings) of the same products identified on each menu. Like Ms. Barr, Dr. Jones does not know the "basis for the decisions about the consumption patterns" devised by Plaintiffs' counsel. Ex. 41, at 106:16–23 (Jones MDL Tr., Vol. I).

C. General Causation Experts

Relying on the opinions of Ms. Barr and Dr. Jones, Plaintiffs offer six experts who testify that exposure to heavy metals in baby foods can cause ASD or ADHD.

1. Epidemiologists. Plaintiffs' three primary causation experts, Drs. Beate Ritz, Hannah Gardener, and Howard Hu are epidemiologists. Their task was to review a group of studies and offer an opinion that there is a causal association between lead *through baby food* and neurological symptoms "diagnosable" as ASD and ADHD and arsenic *through* baby *food* and neurologic

symptoms "diagnosable" as ASD.[41] The opinions of these experts are strikingly similar: each opines that exposure to lead or arsenic through baby food could cause "behaviors that may be diagnosed as" ASD or ADHD—they do not just say that baby food containing some amount of lead or arsenic can cause ASD or ADHD. Ex. 1, at 5 (Ritz MDL Rep.); Ex. 4, at 40 (Hu MDL Rep.); Ex. 7, at 5–6 (Gardener MDL Rep.). Notably, none of these experts has offered or intends to offer such an opinion outside of this litigation.

Dr. Ritz is a professor of epidemiology at UCLA. Ex. 1, at 3 (Ritz MDL Rep.). She has published on environmental exposures and neurodevelopmental outcomes in children, including ASD, but has never published in the peer-reviewed literature an opinion that trace amounts of lead or arsenic in baby food (or any food) can cause ASD/ADHD. In a manuscript Dr. Ritz co-authored after first being retained by Plaintiffs and forming her opinions on the relationship between heavy metals and ASD, entitled "Considering Toxic Chemicals in the Etiology of Autism," Ex. 45 (Ritz Landon R. Tr. Ex. 17, Volk et al. (2022)), Dr. Ritz and her co-authors report a link between lead and childhood IQ in that paper. But the only environmental exposure to lead that the authors linked to autism was air pollution during pregnancy and early infancy at levels of pollution found in large cities.[42] *Id.* When asked why she did not mention her opinions on lead and arsenic from baby food in her academic writings, Dr. Ritz testified that she chose not to do so because "I'm really an air pollution researcher, air pollution and pesticides, so that's what I refer to here, because I know the most about those exposures." Ex. 43, at 170:18–24 (Ritz Landon R. Tr.).

Dr. Gardener holds a faculty position at the University of Miami. Ex. 7, at 3 (Gardener MDL Rep.); Ex. 33, at 59:6–62:21 (Gardener MDL Tr.). Although Dr. Gardener previously published three book chapters on "Pre-, Peri and Neonatal Factors in Autism Etiology" based on her doctoral thesis work, she has not published any peer-reviewed research on ***postnatal*** risk factors for ASD/ADHD. In fact, she did not even mention heavy metals—let alone at the trace levels that may

[41] Dr. Hu's opinions are limited to lead. He does not opine on arsenic.

[42] Dr. Ritz testified that air pollution contains 56 different types of metals that one can measure, and that "it's hard to say" what components or metals in air pollution cause neurotoxicity "because they always come as a mixture together with metals from brake and tire wear, mostly." Ex. 26, at 79:5–80:18 (Ritz MDL Tr.).

be found in food—as one of the "factors in autism etiology" in these pre-litigation publications. Also, despite co-authoring a non-peer reviewed paper that noted heavy metals may be found in various commercial baby foods and other foods, she has never submitted for peer-review her causation opinions in this MDL (and other, related cases) and has no plans to do so. *See* Ex. 46, at 168:2–4 (Gardener Landon R. Tr.).

Dr. Hu is a professor at USC School of Medicine. Ex. 4, at 1 (Hu MDL Rep.). Dr. Hu has spent more than 30 years studying lead and has coauthored over 390 publications and completed multiple population-based studies that examine the impacts of lead exposure on children's health. *Id.* Yet Dr. Hu has not published any peer-reviewed research identifying an association between food that may contain some trace amount of lead and ASD/ADHD. Nor does Dr. Hu have any plans to publish such research in the peer-reviewed literature. Ex. 29, at 36:5–14 (Hu MDL Tr.).[43]

2. Toxicologists. Two other Plaintiffs' experts, Drs. Michael Aschner and Tomas Guilarte, are toxicologists who purport to review (to varying degrees) the same epidemiologic literature as Drs. Ritz, Gardener, and Hu, but admit that they are not trained to employ a Bradford Hill analysis and so invoke instead what they call a "weight of the evidence" standard. The toxicologists also take an additional step by offering their opinions on the alleged biological plausibility of lead as a cause of autism/ADHD and arsenic as a cause of autism. They assert that lead and arsenic may adversely affect any number of biological processes, including (1) causing or exacerbating oxidative stress; (2) impairing DNA methylation; (3) impairment of fetal and infant growth; (4) neuroinflammation; (5) disruption to mitochondrial energy metabolism; (5) effects on synaptic pruning; and (6) NDMA hypofunction. *See* Ex. 34, at 200:6–201:20 (Aschner MDL Tr.); Ex. 10, at 12, 22, 30, 56 (Aschner MDL Rep.); Ex. 35, at 258:7–15 (Guilarte MDL Tr.); Ex. 23, at 27 (Guilarte MDL Rep.). Neither

[43] Dr. Hu has served as a plaintiff's expert testifying to neurological harms in children from lead exposure, including in litigation arising from the Flint, Michigan Water Crisis and Peruvian children's exposure to a metallurgical smelting and refining complex. But Dr. Hu has never testified that lead exposure, even at levels much higher than those seen with baby food, causes ASD/ADHD. *See, e.g.*, Ex. 29, at 48:23–49:3 (Hu MDL Tr.) (testifying only as to the impact of lead on IQ, not ASD/ADHD, for children in Flint, Michigan with changes in blood lead level (BLL) of 5 mcg/dL or below); *id.* at 49:16–51:19 (testifying only as to the impact of lead on IQ, not ASD/ADHD, for Peruvian children with BLLs from 20 to 70 or 75 mcg/dL).

expert claims that any of these mechanisms has been proven to play a causal role in autism/ADHD, let alone that they are triggered by healthful food.

Dr. Aschner is a bench toxicologist whose work is primarily in *in vitro*, non-vertebrate animal models. Ex. 10, at 4 (Aschner MDL Rep.); Ex. 34, at 234:13–16, 84:2–22 (Aschner MDL Tr.). Dr. Aschner has published research regarding exposure to various metals, most significantly manganese and mercury. But he has never claimed, and still does not claim, that consumption of any food can cause ASD or ADHD.

Dr. Guilarte is a neurotoxicologist and Professor of Environmental Health Sciences at Florida International University. Dr. Guilarte has never published research on arsenic and neurodevelopment despite opining on those topics here. Ex. 35, at 40:3–12 (Guilarte MDL Tr.). And despite writing publications opining on the relationship of lead and neurotoxicity, he has published only in the context of rat studies, never human studies, and has never stated in any publication that arsenic or lead—particularly in healthful food—is a cause of ASD/ADHD. *Id.* at 40:17–41:24.

3. Clinical Neurologist. Plaintiff's final expert, Dr. Kevin Shapiro, is a clinical neurologist, who used to be in private practice but now works entirely as a "locum tenens," temporary, physician. Ex. 16, at 1 (Shapiro MDL Rep.). Dr. Shapiro is not an epidemiologist or a toxicologist, and admits that he is neither trained in nor employed any generally accepted method for assessing general causation. Ex. 36, at 17:7–18:10 (Shapiro MDL Tr., Vol. I). He also has not made any attempt to formulate a general causation opinion based on Dr. Jones' exposure calculations. *Id.* at 14:13–21. And he did not review any data on healthy foods, such as baby food. Rather, he appears to claim that all he is offering at this stage is an opinion limited to his view that it is biologically and "clinically plausible" that baby food can cause behaviors or symptoms diagnosable as autism and ADHD. *Id.* at 14:13–15:24. Dr. Shapiro's opinion appears to be that, because environmental exposures are believed to play a role in ASD/ADHD, and lead and arsenic in baby food are environmental exposures children have before the age when ASD/ADHD typically manifest, it makes sense that baby food can cause ASD/ADHD. Based on this personal assessment, Dr. Shapiro even makes the extraordinary claim that consumption of just one carrot can cause ASD. *Id.* at 151:20–152:4.

Not surprisingly, Dr. Shapiro has never submitted the opinions he presents in this case to peer review. In fact, although he recently updated a prior publication on "Evaluation of learning difficulty and cognitive delay" in *BMJ Best Practice* that discussed the causes of autism, he did not add any statement that baby food is a cause. Ex. 37, at 348:10–350:21 (Shapiro MDL Tr., Vol. II) ("I don't recall that I specifically mentioned baby food.").

D. There Is No Scientific Literature Finding that Baby Food, or Any Food, Is Associated with Autism or ADHD, and No Medical or Scientific Organization Has Reached that Conclusion

The claim that baby food can "cause" ASD and/or ADHD has no general acceptance in the scientific community. Plaintiffs' experts cannot identify any peer-reviewed study, scientific report, medical or scientific organization, independent regulatory authority, pediatric society, psychiatric or neurologic society, nutritional society, or medical textbook, treatise, or literature that has concluded consumption of baby food causes ASD or ADHD. *See, e.g.*, Ex. 35, at 48:17–22 (Guilarte MDL Tr.); Ex. 34, at 89:5–14 (Aschner MDL Tr.); Ex. 33, at 261:16–262:15 (Gardener MDL Tr.). Instead, the scientific community and regulatory authorities have repeatedly made clear that eating fruits, vegetables, and grains are critically important for an infant's health in general and for neurodevelopment in particular. The Women, Infants, and Children ("WIC") program, administered by the U.S. Department of Agriculture, provides free healthy foods, including the very baby foods in issue in this litigation, to infants in the United States to ensure they have essential nutrients and are healthy in their growth and development.[44] The nutrients in commercially prepared baby foods are essential for optimal health, including brain health, as the USDA recognizes.[45]

None of the literature reviewed by Plaintiffs' experts evaluates baby food or otherwise measures the impact of baby food on the brain health or neurodevelopment of children—including the potential neuroprotective impacts of nutritious foods. Plaintiffs' experts admit that there are no epidemiological studies demonstrating that consuming baby food is associated with ASD or ADHD.

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[44] *See* USDA, *WIC: USDA's Special Supplemental Nutrition Program for Women, Infants, and Children*, https://www.fns.usda.gov/wic.

[45] *See, e.g.*, USDA, *Dietary Guidelines for Americans, 2020 – 2025*, at 53, https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.

See, e.g., Ex. 35, at 52:9–19 (Guilarte MDL Tr.) (testifying that he could not name any "any peer-reviewed publication that states that there's a causal association between baby food or heavy metals in baby food and ASD or ADHD"); Ex. 34, at 111:21–112:8 (Aschner MDL Tr.) ("There's no studies on baby food and health effects in my report."); Ex. 29, at 303:13–25 (Hu MDL Tr.) (testifying that none of the literature that he considered referenced baby food specifically); Ex. 38, at 12:10–18 (Reed MDL Tr.); Ex. 33, at 250:14–251:19 (Gardener MDL Tr.). None of Plaintiffs' experts have undertaken any original research on baby food or food consumption and ASD or ADHD. *See* Ex. 29, at 36:5–14 (Hu MDL Tr.); Ex. 46, at 168:2–4 (Gardener Landon R. Tr.).[46]

As a result, Plaintiffs' experts seek to stitch together their opinions on the basis of a large variety of studies measuring heavy metals exposures in the body via biomarkers (such as blood, urine, or hair) generally without focus on or controlling for route of exposure and exploring a wide range of generic neurological symptoms. *See, e.g.*, Ex. 16, at 24 (Shapiro MDL Rep.); Ex. 4, at 39 (Hu MDL Rep.); Ex. 13, at 48 (Guilarte MDL Rep.). However, not one of these studies measures exposure from food, and none is limited to the ages when children consume baby foods. Only a few of the studies include a confirmed diagnosis of ASD and ADHD.

As a work-around for the lack of relevant food studies supporting their claim, Plaintiffs' experts point to studies that measure the effect of isolated dietary supplements on either blocking the absorption of heavy metals or therapeutically reducing heavy metal burden in individuals with elevated levels. *See, e.g.*, Ex. 1, at 24–37 (Ritz MDL Rep.); Ex. 16, at 32–33 (Shapiro MDL Rep.); Ex. 7, at 93–109 (Gardener MDL Rep.). They do not address other effects of nutrients, such as beneficially interacting with the mechanisms of harm (for example, oxidative stress). Most significantly, these studies do not assess what happens when children eat diets that contain abundant amounts of vitamins, nutrients, and minerals known to be healthy (even essential) for children's neurodevelopment, including whether those diets somehow cause autism or ADHD.

LEGAL STANDARD

Causation in a personal injury action generally "must be proven within a reasonable medical

[46] As set forth in Sections III.A to III.C of Defendants' brief challenging Plaintiffs' causation experts, they also ignore data that shows no association between healthful food and autism.

probability based upon competent expert testimony." *Kennedy v. S. California Edison Co.*, 268 F.3d 763, 768 (9th Cir. 2001). As part of that inquiry, a plaintiff must prove that "the substance at issue was capable of causing the injury alleged"—*i.e.*, that there is "general causation." *Avila v. Willits Env't Remediation Tr.*, 633 F.3d 828, 836 (9th Cir. 2011). Courts have repeatedly held that the general causation inquiry focuses on the relevant substance or product alleged to have caused harm—not just one subcomponent. *In re Hanford Nuclear Rsrv. Litig.*, 292 F.3d 1124, 1133 (9th Cir. 2002) ("General, or 'generic' causation has been defined by courts to mean whether the substance at issue had the capacity to cause the harm alleged[.]"); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1217 (S.D. Fla. 2022) (MDL court excluded expert opinions based on studies that "did not focus on [Zantac]," but instead "focused on NDMA [a toxin allegedly present in Zantac]"); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1304 (11th Cir. 2014) (concluding that a denture adhesive, which contained zinc compound, was the relevant substance, not zinc by itself); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E.D. Wash. 2009) (because "[g]asoline is a mixture of chemicals, which contains as a small component, benzene," general causation in suit against gasoline manufacturer could not be inferred from studies of benzene alone). Here, the question is: "Can the defendants' products cause these disorders?" Ex. 55, at 40:23–42:3 (June 20, 2024 CMC H'rg Tr.).

Federal Rule of Evidence 702 governs the admissibility of expert testimony, which "always" requires the proponent to "establish the admissibility criteria of Rule 702 by a preponderance of the evidence." *Engilis v. Monsanto Co.*, No. 23-4201, --- F.3d ---, 2025 WL 2315898, at *6 (9th Cir. Aug. 12, 2025). When evaluating proposed expert testimony under the Rule, district courts must carry out the "essential" role of "judicial gatekeeping." Fed. R. Evid. 702 Advisory Committee's note to 2023 amendments. It is "not only appropriate for [the court] to take a hard look at plaintiffs' experts' reports, the court [is] required to do so to ensure reliability." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 982 F.3d 113, 123 (2d Cir. 2020). The court must therefore "scrutinize" proposed testimony to ensure it meets the requirements of Rule 702. Fed. R. Evid. 702 Advisory Committee's note to 2000 amendments; *see also* Fed. R. Evid. 104(a) ("[C]ourt *must* decide any preliminary question about whether a witness is qualified . . . or evidence

is admissible.") (emphasis added). A district court abuses its discretion if it "abdicate[s] its role as gatekeeper" or "delegat[es] that role to the jury." *Est. of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 464 (9th Cir. 2014) (overruled on other grounds); *see also United States v. Valencia-Lopez*, 971 F.3d 891, 898 (9th Cir. 2020) (district court "necessarily abuses its discretion[] when it makes no reliability findings").

Rule 702 sets out five independent admissibility criteria for expert testimony. First, the proponent must show the witness is "qualified as an expert by knowledge, skill, experience, training, or education." Second, the proponent must show the witness's testimony will satisfy each of the Rule's four distinct criteria for reliability and relevance: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case. Fed. R. Evid. 702. The proponent of the expert testimony must "demonstrate[] to the court" each of the admissibility criteria. *Id.*; *see also Engilis*, 2025 WL 2315898, at *8 (witness properly excluded when proponent failed to demonstrate one criterion). "[T]here is no presumption in favor of admission." *Id*. at *6.

Several of Rule 702's standards are especially important here.

First, an expert's opinions must be rooted in reliable data and appropriate studies. Where an expert's opinions are "based on the data from . . . unreliable and unhelpful studies" and the experts do "nothing to verify the validity of [those] studies or results," their opinions are inadmissible. *In re Zantac*, 644 F. Supp. 3d at 1160. Studies not based on the product at issue, but nevertheless claimed to show injury because of a shared ingredient or component are "unhelpful" studies. That is why in *Zantac*, the MDL court excluded expert opinions based on studies that "did not focus on [Zantac]," but instead "focused on NDMA [a toxin allegedly present in Zantac]." *Id*. at 1217. An expert cannot dodge this evidentiary burden nor justify their failure to examine the actual potential exposure at issue by claiming that studies of the exposure at issue do not exist. *See Perry v. Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 467–68 (E.D. Pa. 2008) ("[T]he non-existence of good data does not allow expert witnesses to speculate or base their conclusions on inadequate supporting science.").

If Plaintiffs' experts are unable to identify any literature supporting an association between the exposure at issue (here, baby foods, or for that matter *any* food, that potentially contains trace heavy metals) and the outcomes at issue (here, ASD and ADHD), then Plaintiffs failed to meet that burden. *See Chapman*, 766 F.3d at 1304; *In re Zantac*, 644 F. Supp. 3d at 1104–06; *Burst v. Shell Oil Co.*, No. CIV.A. 14-109, 2015 WL 3755953, at *8 (E.D. La. June 16, 2015), *aff'd*, 650 F. App'x 170 (5th Cir. 2016); *In re Zantac (Ranitidine) Litig.*, No. 255, 2024, 2025 WL 1903760, at *7, *16 (Del. July 10, 2025) (ruling that plaintiffs' experts' view that "'[w]hether [] exposure [to NDMA] comes from food, or from taking a pill every day, does not matter'" was too great an inferential leap, as "ultimately an expert offering an opinion regarding general causation for a product must opine as to the product itself").

Second, an expert's opinion must be based on a reliable scientific methodology and cannot bridge analytical gaps without basis. For a causation opinion to be admissible, an expert must offer a reliable methodology connecting any underlying studies to the specific harm at issue in the litigation. Explaining this standard in the context of a similar claim regarding the causes of ASD and ADHD, Judge Cote recently excluded expert opinions based on studies that did not measure ASD or ADHD and failed to offer a reliable methodology for why examining other endpoints was appropriate. *In re Acetaminophen*, 707 F. Supp. 3d at 340–42. For example, one proffered expert relied on studies purporting to find "lower IQ" among the children of mothers who used acetaminophen during pregnancy because he viewed that symptom as "consistent with ADHD and ASD." *Id*. at 341–42; *see also, e.g.*, *id.* at 364–66. The MDL court excluded the opinions for failing to meet the reliability criteria of Rule 702, finding that the expert failed to bridge the gap between symptoms like "lower IQ" and the relevant harm in the litigation—ADHD and ASD. *Id*. at 342. When "there is simply too great an analytical gap between the data and the opinion proffered," it must be excluded. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

In a causation opinion, this reliability element requires an expert to consider the relevant exposure levels. When faced with expert testimony provided to establish "general causation," a district court must assess whether a qualified expert has offered a reliable opinion that a given substance causes a specific injury "at exposure levels people realistically may have experienced."

Hardeman v. Monsanto Co., 997 F.3d 941, 963 (9th Cir. 2021). Given that requirement, "[i]t's not sufficient for the plaintiffs to present evidence that [an allegedly causative agent] could cause" the relevant injury "at the kinds of massive doses, administered in the kinds of ways, that laboratory animals alone have experienced." *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1113 (N.D. Cal. 2018).

Instead, a general causation opinion here must reliably answer the question whether baby food could have caused ASD and ADHD in "the plaintiffs in these cases"—not in an abstract universe where people are exposed to unlimited, lawyer-invented amounts of Defendants' products. *Id.*; *see also In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prods. Liab. Litig.*, 424 F. Supp. 3d 781, 793 (N.D. Cal. 2020) (general causation inquiry occurs "'at the level of exposure alleged by Plaintiffs'") (quoting *In re Hanford*, 292 F.3d at 1133). The complete "lack of independent scientific support" for an expert's causation opinions casts "doubt on the reliability of [their] methodology" and warrants their exclusion under Rule 702. *In re Zantac*, 644 F. Supp. 3d at 1192; *see also Reyes v. Apple, Inc.*, No. 3:22-CV-02900-JSC, 2025 WL 1223550, at *3 (N.D. Cal. Apr. 28, 2025) (Corley, J.) (finding that whether the theory enjoys general acceptance in the applicable scientific community is a factor that bears on the court's reliability analysis).

Third, an expert cannot cherry-pick studies or facts, nor can they fail to apply adequate intellectual rigor to the task at hand. The "key inquiry" is "whether an expert had sufficient factual grounds on which to draw conclusions." *Hyer v. City & Cnty. of Honolulu*, 118 F.4th 1044, 1056 (9th Cir. 2024) (citation omitted). An expert cannot cherry pick the studies on which he or she relies and "fail[] to address evidence that is highly relevant to his or her conclusion." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018). Instead, the expert must apply the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

CONCLUSION

For all the foregoing reasons and the reasons outlined in the General Causation and Exposure Briefs, the Court should exclude Plaintiffs' experts under Rule 702.

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L.R. 5-1 ATTESTATION

I, Livia M. Kiser, attest that all signatories listed herein, and on whose behalf this filing is submitted, concur in this filing's content and have authorized this filing.

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